



**KDIGO Controversies Conference on**  
**Challenges in the Conduct of Clinical Trials in**  
**Nephrology**

**September 8-11, 2016**  
**Paris, France**

**--- AGENDA ---**

**Thursday, September 8**

**18:00 – 20:00 hrs**

18:00 hrs      **Welcome Reception**  
Location: R'Yves Lounge (1st Floor)

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**Friday, September 9**

**09:00 – 18:00 hrs**

06:30 – 09:00 hrs      **Breakfast Available**  
Location: Galerie (3rd Floor)

**Meeting Overview**

Location: Loft A-E (3rd Floor)

09:00 – 09:15 hrs      **Welcome & Introductions**  
Presenter: John Davis, KDIGO CEO

09:15 – 09:30 hrs      **Conference Overview & Objectives**  
Presenters: Colin Baigent & John McMurray, Conference Co-Chairs

**Plenary Session #1**

Location: Loft A-E (3rd Floor)

09:30 – 10:00 hrs      **Reflections on Trials in Nephrology: Lessons from the Past and Challenges for the Future**  
Presenter: Jonathan Craig

10:00 – 10:30 hrs      **Discussion**

10:30 – 10:45 hrs      **Break**  
Location: Loft F (3rd Floor)

## **Plenary Session #2**

Location: Loft A-E (3rd Floor)

10:45 – 11:15 hrs      **How can we better define outcomes in progression of CKD?**

Presenter: Lesley Inker

11:15 – 11:45 hrs      **Rationale for Choosing Trial Outcomes in Renal Disease**

Presenter: Mike Walsh

11:45 – 12:30 hrs      **Discussion**

12:30 – 13:30 hrs      **Lunch**

Location: Loft G-H (3rd Floor)

## **Plenary Session #3**

Location: Loft A-E (3rd Floor)

13:30 – 14:00 hrs      **Optimizing Trial Design**

Presenter: Martin Landray

14:00 – 14:30 hrs      **Optimizing Trial Execution**

Presenter: Vlado Perkovic

14:30 – 15:15 hrs      **Discussion**

15:15 – 15:30 hrs      **Break**

Location: Loft F (3rd Floor)

## **Plenary Session #4**

Location: Loft A-E (3rd Floor)

15:30 – 16:00 hrs      **Lessons Learned from Recent Trials: Case Studies**

Presenter: Reshma Kewalramani

16:00 – 16:30 hrs      **Dialysis Provider Perspective**

Presenter: Frank Maddux

16:30 – 17:00 hrs	<b>Interpreting Clinical Trials in Nephrology: A Regulator’s Perspective</b> Presenter: Romaldas Mačiulaitis
17:00 – 17:45 hrs	<b>Discussion</b>
17:45 – 18:00 hrs	<b>Wrap-up</b>
18:00 hrs	<b>Adjourn</b> (evening on own)

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**Saturday, September 10**  
**09:00 – 18:15 hrs**

06:30 – 09:00 hrs	<b>Breakfast Available</b> Location: Galerie (3rd Floor)
09:00 – 09:15 hrs	<b>Brief Recap from Day 1</b> Presenter: Colin Baigent & John McMurray Location: Loft A-E (3rd Floor)

**Breakout Session 1**

09:15 – 12:00 hrs	<b>Group A: Renal Outcomes including CKD Progression</b> Discussion Leaders: Joe Coresh & Peter Rossing Location: Studio H-J (2nd Floor)
	<b>Group B: Non-Renal Outcomes in Nephrology Trials</b> Discussion Leaders: Vlado Perkovic & Mike Walsh Location: Studio A-B (2nd Floor)
	<b>Group C: Optimizing Trial Design</b> Discussion Leaders: Martin Landray & Marc Pfeffer Location: Studio D-E (2nd Floor)

**Group D: Optimizing Trial Conduct**

Discussion Leaders: Adeera Levin & Christoph Wanner

Location: Loft A-E (3rd Floor)

12:00 – 13:00 hrs

**Lunch**

Location: Loft G-H (3rd Floor)

**Breakout Group Preliminary Reports & Discussion**

Location: Loft A-E (3rd Floor)

13:00 – 13:45 hrs

**Group A: Renal Outcomes including CKD Progression**

13:45 – 14:30 hrs

**Group B: Non-Renal Outcomes in Nephrology Trials**

14:30 – 15:15 hrs

**Group C: Optimizing Trial Design**

15:15 – 16:00 hrs

**Group D: Optimizing Trial Conduct**

16:00 – 16:15 hrs

**Break**

Location: Loft F (3rd Floor)

**Breakout Session 2**

16:15 – 18:15 hrs

**Group A: Renal Outcomes including CKD Progression**

Discussion Leaders: Joe Coresh & Peter Rossing

Location: Studio H-J (2nd Floor)

**Group B: Non-Renal Outcomes in Nephrology Trials**

Discussion Leaders: Vlado Perkovic & Mike Walsh

Location: Studio A-B (2nd Floor)

**Group C: Optimizing Trial Design**

Discussion Leaders: Martin Landray & Marc Pfeffer

Location: Studio D-E (2nd Floor)

**Group D: Optimizing Trial Conduct**

Discussion Leaders: Adeera Levin & Christoph Wanner

Location: Loft A-E (3rd Floor)

18:15 hrs

**Adjourn**

19:30 hrs

**Group Dinner**

Location: Restaurant Pavillon Montsouris

(Meet in lobby at 19:15 to walk to restaurant. ~12 minute walk from hotel.)

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**Sunday, September 11**

**09:00 to 12:30 hrs**

06:30 – 09:00 hrs

**Breakfast Available**

Location: Galerie (3rd Floor)

**Breakout Group Final Reports and Discussion**

Location: Loft A-E (3rd Floor)

09:00 – 09:45 hrs

**Group A: Renal Outcomes including CKD Progression**

09:45 – 10:30 hrs

**Group B: Non-Renal Outcomes in Nephrology Trials**

10:30 – 11:15 hrs

**Group C: Optimizing Trial Design**

11:15 – 12:00 hrs

**Group D: Optimizing Trial Conduct**

12:00 – 12:30 hrs

**Conference Summation: Next Steps**

Presenters: Colin Baigent & John McMurray